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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,296	09/12/2003	Jagadish C. Sircar	AVANIR.112A	7448
20995	7590	09/14/2006	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			RAHMANI, NILOOFAR	
2040 MAIN STREET			ART UNIT	PAPER NUMBER
FOURTEENTH FLOOR			1625	
IRVINE, CA 92614				

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/661,296	Applicant(s) SIRCAR ET AL.	
	Examiner Niloofer Rahmani	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-46 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, drawn to a pharmaceutical composition for treating or preventing an allergic reaction associated with increased IgE levels or inhibiting cellular proliferation in a mammal comprising any one or more of the compounds in claim 1 wherein one of the Q, T, X, Z being N, classified in class 514, subclass 303+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- II. Claims 1-17, drawn to a pharmaceutical composition for treating or preventing an allergic reaction associated with increased IgE levels or inhibiting cellular proliferation in a mammal comprising any one or more of the compounds in claim 1 wherein two of the Q, T, X, Z being N, classified in class 514, subclass 249+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- III. Claims 1-17, drawn to a pharmaceutical composition for treating or preventing an allergic reaction associated with increased IgE levels or inhibiting cellular proliferation in a mammal comprising any one or more of the compounds in claim 1 wherein three of the Q, T, X, Z being N (fused triazines), classified in class 514, subclass 241+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.

- IV. Claims 1-17, drawn to a pharmaceutical composition for treating or preventing an allergic reaction associated with increased IgE levels or inhibiting cellular proliferation in a mammal comprising any one or more of the compounds in claim 1 wherein four of the Q, T, X, Z being N (fused tetrazines), classified in class 514, subclass 83+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- V. Claim 18-38, drawn to a method for treating or preventing an allergic reaction and /or for inhibiting cytokines or leukocytes in a mammal comprising administering an effective amount of any one or more of the compounds in claim 18 wherein one of the Q, T, X, Z being N, classified in class 514, subclass 303+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- VI. Claim 18-38, drawn to a method for treating or preventing an allergic reaction and /or for inhibiting cytokines or leukocytes in a mammal comprising administering an effective amount of any one or more of the compounds in claim 18 wherein two of the Q, T, X, Z being N, classified in class 514, subclass 249+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- VII. Claim 18-38, drawn to a method for treating or preventing an allergic reaction and /or for inhibiting cytokines or leukocytes in a mammal comprising administering an effective amount of any one or more of the

compounds in claim 18 wherein three of the Q, T, X, Z being N, classified in class 514, subclass 241+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.

- VIII.** Claim 18-38, drawn to a method for treating or preventing an allergic reaction and /or for inhibiting cytokines or leukocytes in a mammal comprising administering an effective amount of any one or more of the compounds in claim 18 wherein four of the Q, T, X, Z being N, classified in class 514, subclass 83+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- IX.** Claim 39-46, drawn to a method of preparation a compound or salt having the formula of Supragenus A, Supragenus B, Supragenus C, Supragenus D wherein one of the Q, T, X, Z being N, classified in class 514, subclass 303+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- X.** Claim 39-46, drawn to a method of preparation a compound or salt having the formula of Supragenus A, Supragenus B, Supragenus C, Supragenus D wherein two of the Q, T, X, Z being N, classified in class 514, subclass 249+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.
- XI.** Claim 39-46, drawn to a method of preparation a compound or salt having the formula of Supragenus A, Supragenus B, Supragenus C, Supragenus D wherein three of the Q, T, X, Z being N, classified in class 514, subclass

241+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.

- XII.** Claim 39-46, drawn to a method of preparation a compound or salt having the formula of Supragenus A, Supragenus B, Supragenus C, Supragenus D wherein four of the Q, T, X, Z being N, classified in class 514, subclass 83+ depending on species election. If this group is elected, a further election of a single disclosed species is also required.

The inventions are distinct, each from the other because of the following reasons:

Groups I-IV compounds are independent and distinct because the structure of each group differ in elements, bonding arrangement and chemical properties to such an extend that a reference anticipating any one group among I-IV would not necessarily render the other groups obvious. The search for each group is not coextensive of the others and separate search and examination must be conducted. Without restriction, a tremendous burden would be imposed on the office to search such diversified subject matter.

Groups V-VIII compounds are independent and distinct because the structure of each group differ in elements, bonding arrangement and chemical properties to such an extend that a reference anticipating any one group among V-VIII would not necessarily render the other groups obvious. The search for each group is not coextensive of the others and

separate search and examination must be conducted. Without restriction, a tremendous burden would be imposed on the office to search such diversified subject matter.

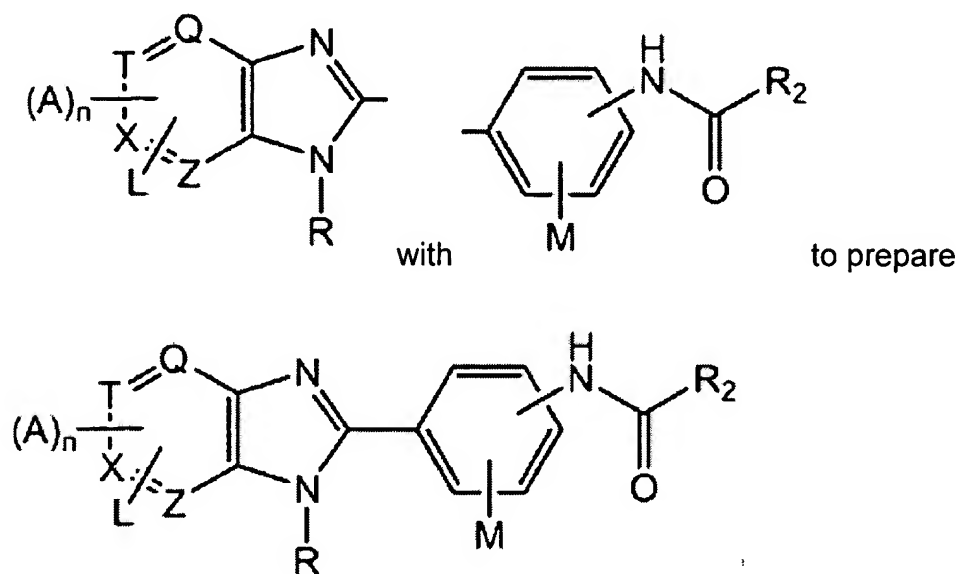
Groups IX-XII compounds are independent and distinct because the structure of each group differ in elements, bonding arrangement and chemical properties to such an extend that a reference anticipating any one group among IX-XII would not necessarily render the other groups obvious. The search for each group is not coextensive of the others and separate search and examination must be conducted. Without restriction, a tremendous burden would be imposed on the office to search such diversified subject matter.

Inventions I-IV and V-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case allergic reaction can be treatable by anti histamine drugs.

Inventions I-IV and IX-XII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed

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can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compounds claimed can be prepared by the coupling reactions such as



The examiner has required restriction between product and process claims.

Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is *presented prior* to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus to be **allowable**, the rejoined claims must meet all criteria for patentability including the

requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*; *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include all the limitations of the product claims. *Applicants are reminded of propriety of process of use claims in consideration of the "reach-through" format, which is drawn to mechanistic, receptor binding or enzymatic functionality. Reach through claims are considered lacking of descriptive and enabling support from the specification. Thus, rejoinable process of use claims are those with particular disease named with efficacy support from the specification for treating the particular disease. Failure to do so may result in a loss of the right to rejoinder.*

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01. Filing of appropriate terminal disclaimer in anticipation of a rejoinder may speed prosecution and the process of rejoinder.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI

09/11/2006

NR



THOMAS MCKENZIE

SPE

GROUP 1625